REMARKS

In response to the Office Action mailed April 13, 2009, claims 1, 4, 8, and 18 have been amended. Claims 2, 6, 7, 10, and 19 have been canceled and no new claims have been added. Support for all of the above amendments can be found throughout the as-filed specification and original claims, for example, on pages 13-14, and in original claims 2, 6, 7, 10, and 19. No new matter has been added. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 1, 4, 8, 11-18, and 20-23 are pending and under examination. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

CLAIM REJECTIONS UNDER 35 U.S.C. §112, INDEFINITENESS

Claims 6-8 and 17 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner alleges that claims 6-8 have insufficient antecedent basis for the limitation "the interaction molecule" and that claim 17 has insufficient antecedent basis for the limitation "the cellular adhesion molecule". Applicants respectfully submit that claim 1 has been amended, without acquiescence, to clarify particular aspects of the presently claimed invention, and that all claim terms now have proper antecedent basis; thus, obviating this basis for rejection. Reconsideration and withdrawal of this basis for rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §112, WRITTEN DESCRIPTION

Claims 1, 2, 4, 6-8, and 10-23 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse this basis for rejection and submit that the as-filed specification amply describes the presently claimed invention. Moreover, one having ordinary skill in the art would recognize that Applicants were in possession of the entire claimed breadth of the presently claimed invention at the time the instant application was filed.

As noted in the "Remarks" section, the claims have been amended without acquiescence to more clearly recite particular aspects of the presently claimed invention. Amended claim 1 recites:

> "A composition comprising:
>
> a) a cellular adhesion related agent, wherein the cellular adhesion related agent comprises an interaction substance interacting with a cellular adhesion molecule and wherein the interaction substance is an antibody or a derivative thereof; and
>
> b) a target substance comprising a genetic material;
>
> wherein the composition enhances the introduction efficiency of the target substance into a cell."

Applicants respectfully submit that support for amended claim 1 can be found throughout the as-filed specification and original claims and thus, does not contain new matter.

The Examiner alleges that the as-filed specification does not provide a description of the broadly claimed cellular adhesion related agents, interaction substances that interact with a cellular adhesion molecule, or gene introduction reagents. Applicants respectfully disagree.

Applicants respectfully submit that the as-filed specification discloses a cellular adhesion related agent as an agent suppressing the adhesion of a cell to another substance such as a support, other cells or the like. Such an agent includes, but is not limited to interaction substances which interact with a cellular adhesion molecule.

Applicants submit that cell adhesion molecules are adequately described in the as-filed specification and well-known in the art (for example, see page 13, lines 17-23 and page 14, lines 17-27 of the as-filed specification and Elangbam et al. (copy attached)).

Applicants respectfully submit that the as-filed specification discloses that an interaction substance includes, but is not limited to, for example, a substance that allosterically interacts with a competitor, a partner in an antigen-antibody reaction (an antibody when the partner is an antigen, and an antigen when the partner is an antibody), a partner in a receptor-ligand relationship (a ligand when the partner is a receptor, and a receptor when the partner is a ligand), and the like. One having skill in the relevant art would appreciate that the interaction substance need only interact with a particular cell adhesion molecule on the target cell to enhance the introduction efficiency of a target substance (e.g., a genetic material) into the cell, as presently claimed.

Applicants respectfully point out that the presently claimed interaction substance is an antibody or a derivative thereof. Applicants submit that antibodies for cell adhesion molecules are exemplified in the as-filed specification and were well known in the art at the time of filing the instant application. Moreover, one having skill in the art could easily generate antibodies specific to a given cell adhesion molecule, as the polypeptide sequences of said molecules were known and the methods of making antibodies were well known to those having ordinary skill in the art at the time the instant application was filed. Applicants submit that information which is well known in the art need not be described in detail in the specification. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1993). Thus, one having skill in the art would believe Applicants to be in possession of the presently claimed interaction substances at the time the instant application was filed.

Applicants respectfully submit that the skilled artisan would immediately recognize that by enhancing the cellular adhesion, the efficiency of introducing genetic material into a cell is increased. Applicants further submit that the as-filed specification clearly describes and exemplifies these concepts in such a manner that the skilled artisan would reasonably conclude Applicants to be in possession of the entire claimed breath of the presently claimed invention at the time the instant application was filed. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed

invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Accordingly, Applicants submit that the as-filed specification comports with §112, first paragraph and respectfully request that this basis for rejection be considered and withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §102(B), FIRST REJECTION

Claims 1, 2, 4, 6-8, 10-19, 22, and 23 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Scott et al. (J of gene Medicine, 2001, 3:125-134), as evidenced by GIBCO product insert for OPTI-MEM® (Form No. 2017, June 2001, one page) and Kamata et al. (J of Biological Chemistry, 1994, 269, 26006-26010). Specifically, the Examiner contends that Scott et al. teach all the limitations of the claims and therefore, anticipate the presently claimed invention.

Applicants respectfully traverse this basis for rejection and submit that Scott et al. fail to anticipate the presently claimed invention because they do not teach each and every element of the claims as arranged in the claims. The Federal Circuit has held that "[b]ecause the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102 --must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

As noted above, Applicants, without acquiescence, have amended the claims to more clearly recite particular aspects of the invention. For example, the present claims require a composition comprising an interaction substance that is an antibody or derivative thereof and a genetic material, wherein the composition enhances the introduction efficiency of the target substance into a cell.

The Examiner alleges that Scott et al. teach a composition comprising all of: a peptide comprising the integrin-binding motif "RGD", cationic liposome, anti-CD29 antibody (anti-(31 integrin polyclonal antibody) and salts comprised in OPTI-MEM® media (p. 127, col. 1

bridging to col. 2). The Examiner further alleges that Scott et al. teach that the cationic liposome serves as a gene introduction agent and both anti-CD29 antibody and the RGD peptide would be interaction substances that interact or bind with integrin. Applicants respectfully disagree.

Applicants respectfully submit that Scott et al. fail to teach a composition comprising an interaction substance that is an antibody or derivative thereof and a genetic material, wherein the composition enhances the introduction efficiency of the target substance into a cell. In contrast, Scott et al. clearly teach two separate compositions. Scott et al. teach a first composition comprising an integrin antibody that contacts cells "before transfection" (see Scott et al. p.130, 1st column) in order to block the second composition, e.g., lipopolyplex composition, from transfecting the cell. Scott et al. plainly disclose the lipopolyplex composition "consisting of a plasmid DNA, a bipartite peptide with ligand and DNA-binding properties, and a cationic liposome" (see Scott et al. p. 133, 2nd column).

Moreover, Scott et al. teach that the use of any of three integrin antibodies decreased transfection efficiency by up to 70%, e.g., the introduction efficiency of the genetic material (see Scott et al. p.130, 1st column, and p. 133, 1st column), in contrast to the presently claimed composition, which increases the introduction efficiency of genetic material.

Thus, Applicants submit that the Examiner has erred in combining the separable compositions of Scott et al. in order to deprecate the presently claimed compositions. Clearly, Scott et al. do not teach the presently claimed compositions comprising each and every element as arranged in the claims; thus, Scott et al. fail to anticipate the presently claimed invention.

Accordingly, reconsideration and withdrawal of this basis for rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §102(B), SECOND REJECTION

Claims 1, 2, 4, 6-8, 10-17, 20, and 21 stand rejected under 35 U.S.C. §102(b) as being anticipated by Felsenfeld et al (Nature, 1996, 383:438-440). Specifically, the Examiner contends that Felsenfeld et al. teach all the limitations of the claims, but that recitation of "for enhancing the introduction efficiency of a target substance into a cell" in the preamble is merely

suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. Therefore, the Examiner contends that Felsenfeld et al. anticipate the presently claimed invention.

Applicants respectfully traverse this basis for rejection and submit that Felsenfeld et al. fail to anticipate the presently claimed invention because they do not teach each and every element of the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California* , 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As noted above, Applicants, without acquiescence, have amended the claims to more clearly recite particular aspects of the invention. For example, the present claims require a composition comprising an interaction substance that is an antibody or derivative thereof and a genetic material, wherein the composition enhances the introduction efficiency of the target substance into a cell. Applicants respectfully point out the claim 1 has been amended to recite wherein the composition enhances the introduction efficiency of the target substance into a cell in the body of the claim; thus, Applicants submit that the Examiner should properly give this element patentable weight and include said element in any determinations of patentability.

Applicants submit that Felsenfeld et al. teach a composition comprising an anti-integrin antibody conjugated to a colloidal gold particle. Felsenfeld et al. fail to teach the introduction of genetic material into a cell, as presently claimed. In addition, nowhere in the entirety of the Felsenfeld et al. reference is there any disclosure or suggestion of a composition comprising an interaction substance that is an antibody or derivative thereof and a genetic material, wherein the composition enhances the introduction efficiency of the target substance into a cell. In fact, Felsenfeld et al. merely use the colloidal gold antibody to observe patterns of cell movement, and are completely silent with regard to contemplating the introduction of genetic material into a cell, as presently claimed.

Accordingly, Applicants submit that Felsenfeld et al. fail to anticipate the presently claimed invention because they do not teach each and every element of the claims. Reconsideration and withdrawal of this basis for rejection is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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